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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/705,286 | 11/02/2000 | WeiHong Xiong | T8341.NP | 4704 |

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EXAMINER

GHALI, ISIS A D

| | |
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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/705,286

Applicant(s)

XIONG ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 29-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS, filed 7/8/2002; declaration, power of attorney and fee, filed 7/16/2002; and election filed 10/01/2002.

Response to Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-29, and species A, claim 28, in Paper No. 6 is acknowledged.
2. Claims 29-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II and species B, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 7/8/2002 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, applicant recites biologics. It is not clear to the examiner as the breadth of such word since the terms "permeation enhancers" constitute biologics, what additional limitation does the term impart.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the

claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation fatty acid esters, and the claim also recites fatty acid esters of lactic acid and fatty acid esters of glycolic acid, which is the narrower statement of the range/limitation.

Claim 6, at the end of the first line, there is letter "w" standing by itself, and the examiner believes that it is a typographical error

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 6,352,715 ('715), US 6,159,986 ('986) or CN 1111987 ('987).

US '715 teaches a transdermal drug delivery system to administer huperzine A in a controlled release skin patch designed for once-a-week application. The device comprises a solvent to form a reservoir or it may contain a pressure sensitive adhesive polymer (abstract; col.3, lines 55-65; col.4, lines 7-15; col.9, lines 1-7, 31). The reference teaches a combination of co solvents to increase the skin permeation of huperzine (col.8, lines 65-67).

US '986 teaches a therapies and compounds for the inhibition of memory loss comprising transdermal administration of huperzine A in combination with plant extract, antioxidants, herbs (e.g. ginkgo, ginseng, Echinacea), amino acids, vitamins, and delivery enhancer (abstract; col.2, lines 6-20, 62; col.3, lines 8-18).

CN '987 teaches a plaster for treating senile dementia with long activity life of 3-4 days comprising huperzine and permeation enhancer (abstract).

The references do not teach the specific permeation enhancers claimed by applicants, the blood plasma levels, or the estrogen in combination with huperzine.

Fatty acids, fatty acid esters, fatty alcohols, surfactants, terpenes, and pyrrolidone derivatives are all known in the art as permeation enhancer, and are widely used in the transdermal art.

It is within the skill in the art to adjust the amount of the drug in order to achieve a therapeutic blood level for a predetermined period.

Transdermal delivery of combination of drugs is known and widely used in the transdermal devices. No criticality has been shown in using estrogen in combination with huperzine in improving cognitive function.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal drug delivery device to deliver huperzine as disclosed by any of US '715, US '986 or CN '987, and include any of the permeation enhancers in the formulation as desired by any of the references, with reasonable expectation of success of the delivered transdermal patch in improving memory and cognitive function in patients in need.

10. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 6,352,715 ('715), US 6,159,986 ('986) or CN 1111987 ('987), in combination with US 6,019,988 ('988).

The teachings of US '715, US '986 and CN '987 are discussed above. The references, however, do not teach the specific permeation enhancers claimed by applicants, the blood plasma levels, or the estrogen in combination with huperzine.

US '988 teaches transdermal patches to deliver drugs such as acetylcholine esterase inhibitors comprising permeation enhancers selected from fatty acids, fatty alcohols, fatty acid esters, terpenes, surfactants, and pyrrolidone derivatives (col.19, line 15; col.20, lines 53-65).

It is within the skill in the art to adjust the amount of the drug in order to achieve a therapeutic blood level for a predetermined period.

Transdermal delivery of combination of drugs is known and widely used in the transdermal devices. No criticality has been shown in using estrogen in combination with huperzine in improving cognitive function.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal drug delivery device to deliver huperzine as disclosed by any of US '715, US '986 or CN '987, and include any of the permeation enhancers in the formulation as desired by any of the references, motivated by the teaching of US '988 that the method and composition that increase the skin permeation of the drug increase the bioavailability of the drug into the systemic circulation, col.5, lines 15-19, with reasonable expectation of success of the delivered transdermal patch in improving memory and cognitive function in patients in need.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,663,344 disclosed a treating Alzheimer' disease using huperzine administered transdermally.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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